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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,166	01/12/2004	Mark B. Knudson	14283.1USI6	2117

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 04/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,166	KNUDSON ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8 and 20-23, drawn to a method, classified in class 607, subclass 48.

II. Claim 9, drawn to an apparatus, classified in class 607, subclass 2.

III. Claims 10-16, drawn to a method, classified in class 607, subclass 3.

IV. Claims 17-19, drawn to a method, classified in class 607, subclass 46.

V. Claim 24, drawn to a method, classified in class 607, subclass 3.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another and materially different apparatus, such as an apparatus which does not include an electrically controllable neural conduction electrode adapted to be placed on a vagus nerve at a blocking site and a blocking signal generator, but the process may be practiced an apparatus such as combination implantable pulse generator (for the electrical stimulation portion of the method) and implantable drug delivery device (for the neural conduction blocking portion of the method) which applies a neural conduction block that is a cryogenic block or a pharmacologic block.

3. Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require

the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not include the step of determining that an involuntary movement is going to occur and the combination does not require that the stimulation be applied to the vagus nerve at a point below the inferior cardiac nerve. The subcombination has separate utility such as by itself or with a method that applies an electrical neural conduction block.

4. Inventions I and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require that the electrical stimulation signal be a "pulse", the combination does not require that the signal be applied directly or indirectly to the vagus nerve at a location in the immediate vicinity of the patient's diaphragm and the combination further does not require the step of "selectively programming" the electrical and timing parameters of the stimulation signal. The subcombination has separate utility such as by itself or with a method that applies an electrical neural conduction block.

5. Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and they have different modes of operation and different

effects. Specifically, Invention V does not require that the stimulation and blocking be applied to a patient's vagus nerve as opposed to the limitations of Invention I. In addition, Invention I does not require that the neural conduction block be an electrical neural conduction block, but rather Invention I may be practiced by an apparatus such as combination implantable pulse generator (for the electrical stimulation portion of the method) and implantable drug delivery device (for the neural conduction blocking portion of the method) which applies a neural conduction block that is a cryogenic block or a pharmacologic block. Also, Invention I does not require any programming of the stimulation and/or neural conduction blocking.

6. Inventions III and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another and materially different apparatus, such as an apparatus which does not include an electrically controllable neural conduction electrode adapted to be placed on a vagus nerve at a blocking site and a blocking signal generator, but the process may be practiced an apparatus such as combination implantable pulse generator (for the electrical stimulation portion of the method) and implantable drug delivery device (for the neural conduction blocking portion of the method) which applies a neural conduction block that is a cryogenic block or a pharmacologic block.

7. Inventions IV and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to

practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another and materially different apparatus, such as an apparatus which does not include an electrically controllable neural conduction electrode adapted to be placed on a vagus nerve at a blocking site and a blocking signal generator, but the process may be practiced an apparatus such as combination implantable pulse generator (for the electrical stimulation portion of the method) and implantable drug delivery device (for the neural conduction blocking portion of the method) which applies a neural conduction block that is a cryogenic block or a pharmacologic block.

8. Inventions V and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process, such as a process which does not include any programming of the electrical and timing parameters of the electrical stimulation and/or neural conduction blocking but rather the apparatus may be used in a process where the electrical and timing parameters of the electrical stimulation and/or neural conduction blocking are present into the memory and/or microprocessor of the device and are unchangeable or unprogrammable. In addition, the process as claimed can be practiced by another and materially different apparatus, such as an apparatus that does not include electrodes positioned on the vagus nerve. The process as claimed may be practiced with any apparatus which places electrodes on any cranial nerve other than the vagus nerve.

9. Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the step of "selectively programming" the electrical and timing parameters of the stimulation signal. The subcombination has separate utility such as by itself or with a method that applies an electrical neural conduction block.

10. Inventions V and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require stimulation and blocking be applied to the vagus nerve and the combination further does not require determining that an involuntary movement is going to occur and thereafter applying stimulation. The subcombination has separate utility such as by itself or with a method that applies an electrical stimulation and/or neural conduction block to any cranial nerve other than the vagus nerve.

11. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and they have different modes of operation and effects.

Specifically, Invention V does not require that the stimulation and blocking be applied to a patient's vagus nerve as opposed to the limitations of Invention IV. In addition, Invention IV does not require that the neural conduction block be an electrical neural conduction block, but rather Invention IV may be practiced by an apparatus such as combination implantable pulse generator (for the electrical stimulation portion of the method) and implantable drug delivery device (for the neural conduction blocking portion of the method) which applies a neural conduction block that is a cryogenic block or a pharmacologic block.

12. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

13. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel 04/25/06
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766